K081330

K081332

7. 510(k) Summary

JUN 10 2008

Sponsor:	SIGNUS Medizintechnik GmbH Carl-Zeiss-Strasse 2 D-63755 Alzenau, GERMANY Tel. + 49 (0) 6023 9166-136 Fax + 49 (0) 6023 9166-161 Url: http://www.signus-med.de
Contact Person:	Jörg Degen, Regulatory Affairs, QM
Proposed Trade Name:	ATHLET™ VBR
Device Classification	Class II
Classification Name:	Spinal vertebral body replacement device
Regulation:	888.3060
Device Product Code:	MQP
Device Description:	The ATHLET™ VBR System is a lordotic, modular vertebral body replacement system. Caudal and cranial components are offered in a variety of heights and are assembled to create a device construct. An intermediate component is also available and is used between one caudal and one cranial component. The device construct comprises a central cannula for bone graft and lateral fenestrations for bony in-growth.
Intended Use:	The ATHLET™ VBR is indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a vertebral body replacement in the thoracolumbar spine (from T1 to L5). The ATHLET™ System is intended for use with supplemental fixation and should be implanted in pairs.
Materials:	The ATHLET™ VBR components are manufactured from polyetheretherketone (PEEK-OPTIMA® LT1, Invibio™) as described by ASTM F2026. Integral marker pins are manufactured from titanium alloy (Ti-6Al-4V) as described by ASTM F136.
Substantial Equivalence:	Documentation was provided which demonstrated the ATHLET™ VBR to be substantially equivalent to previously cleared vertebral body replacement devices. The substantial equivalence is based upon equivalence in basic design, intended use, indications, anatomic sites and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SIGNUS Medizintechnik GmbH
% Karen E. Warden, Ph.D.
Representative/Consultant
8202 Sherman Road
Chesterland, Ohio 44026

JUN 10 2008

Re: K081332
Trade/Device Name: ATHLET™ VBR
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: MQP
Dated: May 12, 2008
Received: May 12, 2008

Dear Dr. Warden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K081332

Device Name: **ATHLET™ VBR**

Indications for Use:

The ATHLET™ System is indicated for use to replace a vertebral body that has been resected or excised due to tumor or trauma/fracture. The device is intended for use as a vertebral body replacement in the thoracolumbar spine (from T1 to L5). The ATHLET™ system is intended for use with supplemental internal fixation and intended to be implanted in pairs.

Prescription Use X OR Over-the-Counter Use_____

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for mxm

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081332